# Complete Summary

#### **GUIDELINE TITLE**

Emergency contraception.

# BIBLIOGRAPHIC SOURCE(S)

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Emergency contraception. Aberdeen (Scotland): Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit; 2003 Jun. 7 p. [53 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

# COMPLETE SUMMARY CONTENT

SCOPE

**DISCLAIMER** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

#### SCOPE

# DISEASE/CONDITION(S)

- Unprotected sexual intercourse
- Sexual intercourse with potential contraceptive failure
- Unintended pregnancy
- Sexually transmitted infection (STI)

# **GUIDELINE CATEGORY**

Counseling Management Prevention

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

#### INTENDED USERS

Advanced Practice Nurses Nurses Patients Pharmacists Physician Assistants Physicians

# GUIDELINE OBJECTIVE(S)

To provide recommendations and good practice points on the use of emergency contraception

#### TARGET POPULATION

Women seeking emergency contraception

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Medical history (including sexual history) and clinical examination; testing for Chlamydia trachomatis
- 2. Counseling patients regarding emergency contraception to help them make informed choices
- 3. Emergency contraception including:
  - Oral progestogen-only emergency contraception (POEC) (levonorgestrel [Levonelle, Levonelle-2])
  - Copper intrauterine contraceptive devices (IUDs)

Note: Mifepristone has been shown to be an effective emergency contraception when taken as a single dose up to 120 hours after unprotected sexual intercourse. However, it is not licensed nor readily available for this indication in the UK.

4. Follow-up including pregnancy test if needed and information and counseling on use of contraceptive methods

#### MAJOR OUTCOMES CONSIDERED

- Safety, efficacy, and cost-effectiveness of emergency contraception
- Failure rates of emergency contraception
- Drug interactions and side effects associated with emergency contraception

#### METHODOLOGY

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic searches were performed for MEDLINE (1996-2002); EMBASE (1996-2002); the Cochrane Library (to 2002), and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms, and text words. The Cochrane Library was searched for systematic reviews, meta-analyses, and controlled trials relevant to emergency contraception (EC). Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO), and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organizations.

Evidence tables (available on the Faculty Web site [www.ffprhc.org.uk]) summarise relevant published evidence on emergency contraception (EC), which was identified and appraised in the development of this Guidance.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation based on levels of evidence as follows:

- A: Evidence based on randomised controlled trials (RCTs)
- B: Evidence based on other robust experimental or observational studies
- C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

#### COST ANALYSIS

Emergency contraception (EC) appears to be cost-effective, whether it is provided on request or as an advance supply to be used when needed. A greater use of EC could reduce the medical and social costs of unintended pregnancy.

#### METHOD OF GUIDELINE VALIDATION

Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

Definitions of the grades of recommendation, based on levels of evidence (A-C, Good Practice Point), are provided at the end of the "Major Recommendations" field.

What regimens are available?

- 1. Progestogen-only emergency contraception (POEC) should be started as soon as possible and within 72 hours of unprotected sexual intercourse (UPSI) or potential contraceptive failure (Grade B).
- 2. Currently in routine practice, one tablet containing 0.75 mg levonorgestrel (LNG) should be given and repeated 12 hours later (Grade A).
- 3. In situations where patient compliance is likely to be poor, POEC may be given as a single dose of 1.5 mg LNG (Grade A).

- 4. A copper intrauterine contraceptive device (IUD) can be inserted up to 5 days after the first episode of UPSI or up to 5 days after the expected date of ovulation in a regular cycle (Grade C).
- 5. The intrauterine contraceptive system (IUS) should not be used as emergency contraception (EC) (Grade C).
- 6. An IUD containing more than 300 mm<sup>2</sup> of copper should be used if technically possible (Grade B).

Ideally, the second dose of POEC should be taken 12 hours after the first. However, the interval between doses may be up to 16 hours if this improves compliance (Good Practice Point).

Ideally, an emergency IUD should be fitted at first presentation, but can be offered at the woman's convenience. In this case POEC should be given if within 72 hours of UPSI or potential contraceptive failure (Good Practice Point).

If facilities are unavailable for emergency IUD insertion, local referral mechanisms should facilitate access to a specialist who can provide this service (Good Practice Point).

POEC can be used more than once in a cycle if clinically indicated (Good Practice Point).

What drug interactions are relevant to EC use?

- 7. Women using liver enzyme inducers should take two tablets (1.5 mg) at first presentation followed by one tablet (0.75 mg) 12 hours later and be advised regarding alternative use of an IUD (Grade C).
- 8. Women using non-enzyme-inducing antibiotics should follow the normal POEC regimen (Grade C).

What aftercare and follow-up is required?

- 9. Women should be instructed to return for a pregnancy test if their expected menstruation is more than 7 days late, or lighter than usual (Grade B).
- 10. POEC does not provide contraceptive cover for the remainder of the cycle and effective contraception or abstinence must be advised (Grade B).
- 11. An IUD can be removed anytime after the next menstruation if no UPSI has occurred since menses or if hormonal contraception has been started within the first 5 days of the next cycle (Grade C).

Information and counselling should be provided to women on use of their contraceptive method of choice (Good Practice Point).

Following missed pills, women should be advised to resume hormonal contraception at their usual time as long as this is within 12 hours of the second dose of POEC (Good Practice Point).

How effective is EC?

- Women should be fully counselled regarding the failure rates of oral and intrauterine EC to allow them to make an informed choice (Good Practice Point).
- An IUD should be offered to all women attending for EC even if presenting within 72 hours of UPSI (Good Practice Point).

# When is EC indicated?

# Recommendations for EC Use with Potential Failures of Various Contraceptive Methods

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Method of Contraception	Indications for emergency contraception
Combined pills (21 active tablets)	<ul> <li>Indicated if two or more pills have been missed from the first seven pills in a packet and the woman has had UPSI either in the pill-free week or in the first 7 days of the packet. The combined oral contraception (COC) should be continued with additional barrier contraception until pills have been taken on 7 consecutive days.</li> <li>Indicated if four or more pills have been missed from the middle seven pills in the packet and UPSI has occurred in the 7 days since missing the fourth pill. The combined pill should be continued with additional barrier contraception until pills have been taken on 7 consecutive days.</li> <li>Indicated if there has been a failed barrier method or UPSI during short-term antibiotic use or in the 7 days after antibiotic treatment is completed.</li> <li>Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme-inducing drugs.</li> </ul>
Progestogen-only pill (POP)	<ul> <li>Indicated if one or more POPs have been missed or taken more than 3 hours late and UPSI has occurred in the 2 days following this. The POP should be continued with additional barrier contraception until pills have been taken correctly on two consecutive days.</li> <li>Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducers.</li> </ul>
Intrauterine device	If complete or partial expulsion is identified or mid-cycle removal of the IUD is deemed necessary EC should be considered.
Medroxyprogesterone acetate (Depo-Provera)	Indicated if the contraceptive injection is late (more than 14 weeks from the previous injection) and UPSI has occurred.

Method of Contraception	Indications for emergency contraception
	Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme-inducing drugs.

Professionals should present the evidence of the effectiveness and need for EC in individual situations to allow women to make an informed choice regarding its use (Good Practice Point).

Are there any contraindications to EC?

- 12. There are no absolute contraindications to the use of POEC but caution should be used in women with porphyria or severe liver disease (Grade C).
- 13. Use of the copper IUD for EC should follow the same relative and absolute contraindications as for routine IUD use (Grade C).

What are the side effects of EC?

- 14. Women should be advised that menstrual irregularity can occur within the cycle following POEC use (Grade A).
- 15. If vomiting occurs within 2 hours of taking either dose of POEC, a further dose, anti-emetics, or an IUD should be advised (Grade C).
- 16. Domperidone maleate is a suitable anti-emetic for women with previous vomiting following POEC or persistent vomiting during current use (Grade C).
- 17. Women should be counselled regarding a six-fold increase in the risk of pelvic infection in the 21 days following insertion of an IUD. They should be told how to recognise symptoms and when to seek medical advice (Grade B).

Women should be provided with written information on how to access help and advice should any side effects occur (Good Practice Point).

The possibility of an ectopic pregnancy should be considered if POEC has failed or where an abnormal bleeding pattern follows its use (Good Practice Point).

What clinical examination and investigation is needed before providing EC?

- 18. A sexual history should be taken from all those attending for EC to assess risk of sexually transmitted infection (STI) and other sexual health issues (Grade C).
- 19. Prior to emergency IUD insertion those at high risk should be tested for STIs, particularly Chlamydia trachomatis (Grade C).
- 20. The use of prophylactic antibiotics routinely at the time of emergency IUD insertion cannot be recommended but in high-risk groups their use may be considered (Grade C).

For high-risk women undergoing emergency IUD insertion, antibiotics and abstinence may be advised after testing and pending results. Azithromycin 1 gram

stat or doxycycline 100 milligrams twice daily for 7 days are suitable regimens (Good Practice Point).

Service providers should offer STI screening to all those attending for EC (Good Practice Point).

Who can supply EC?

- 21. Patient Group Directions (PGDs) should be developed locally to facilitate nurse and pharmacist supply and administration of POEC in different clinical and community settings (Grade B).
- 22. Adequate training for clinical and support staff involved in services providing EC should be provided (Grade B).

Managed clinical care pathways should be developed locally to promote integrated working between different service providers to ensure good access, counselling, and quality of care (Good Practice Point).

Should EC be provided in advance of need?

23. Advanced provision of POEC and instructions on use can be offered to those attending family planning and sexual health services (Grade A).

Providers of family planning and sexual health services should work together with other providers and local health authorities to collect data on use of EC and pregnancy rates (Good Practice Point).

#### Definitions

Grades of Recommendation based on levels of evidence as follows:

- A: Evidence based on randomised controlled trials (RCTs)
- B: Evidence based on other robust experimental or observational studies
- C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

CLINICAL ALGORITHM(S)

None provided

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations" field).

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

- Appropriate use of emergency contraception
- Prevention of unintended pregnancy

#### POTENTIAL HARMS

Adverse effects and drug interactions associated with emergency contraception:

#### Levonorgestrel:

- Disturbances in the timing of the next menses
- Vomiting occurs in 5.6% of women
- Nausea is reported in 23.1% of women
- On theoretical grounds due to its effects on tubal motility, pregnancy following progestogen-only emergency contraception (POEC) use may be more likely to be ectopic than in the general population but there are insufficient post-marketing data to allow accurate assessment of risk.
- Caution is advised when prescribing (POEC) for women using warfarin and women with porphyria or severe liver disease

#### Copper Intrauterine Contraceptive Device (IUD):

• Infective morbidity is related to insertion of IUD in the presence of infection rather than to the use of IUD itself. The risk of pelvic infection is increased 6.3-fold in the 21 days following IUD insertion. There is no continued increased risk with continuing use, unless exposed to new infection.

# CONTRAINDICATIONS

#### **CONTRAINDICATIONS**

- There are no absolute contraindications to the use of progestogen-only emergency contraception (POEC)
- Relative contraindications to POEC are the same as for routine use of Levonelle:
  - Severe hypertension
  - Diabetes mellitus with associated vascular complications or neuropathy
  - Ischemic heart disease
  - Stroke
  - Past history of breast cancer
- Use of the copper intrauterine contraceptive device (IUD) for emergency contraception should follow the same relative and absolute contraindications as for routine IUD use (refer to the Faculty of Family Planning and

Reproductive Health Care [FFPRHC] guideline The Copper Intrauterine Device as Long-Term Contraception).

# IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness Timeliness

# IDENTIFYING INFORMATION AND AVAILABILITY

# BIBLIOGRAPHIC SOURCE(S)

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Emergency contraception. Aberdeen (Scotland): Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit; 2003 Jun. 7 p. [53 references]

**ADAPTATION** 

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jun

GUI DELI NE DEVELOPER(S)

Faculty of Family Planning and Reproductive Health Care - Professional Association

SOURCE(S) OF FUNDING

Faculty of Family Planning and Reproductive Health Care

**GUI DELI NE COMMITTEE** 

#### Clinical Effectiveness Committee

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#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDFLINE STATUS**

This is the current release of the guideline.

# **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the <u>Faculty of Family Planning and Reproductive Health Care Web site</u>.

Print copies: Available from the Faculty of Family Planning and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

#### AVAILABILITY OF COMPANION DOCUMENTS

None available

#### PATIENT RESOURCES

None available

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